

**REMARKS**

Claims 70-72, 74-77, 79-80, 85, 99, 105-106, 108-111, 113-114, 119, 133, and 139-148 are pending in the application. Claims 105-106, 108-111, 113-114, 119, and 133 are withdrawn. Claims 70 and 141 have been amended. Support for the amendment to claim 70 may be found at least, e.g., at page 42, lines 8-15. Support for the amendment to claim 141 may be found at least, e.g., at page 45, line 33 to page 46, line 4 of the specification as filed. No new matter has been added.

Claim Objections

Claims 140-142 are objected to as being of improper dependent form for allegedly failing to further limit the subject matter of a previous claim. Claim 70 has been amended to recite that the mammal is otherwise free of indications for treatment with IFN- $\beta$ . Claim 141 has been amended to depend from claim 70. Applicant respectfully submits that claims 140-142 are of proper dependent form and requests withdrawal of this objection.

Claim rejections under 35 U.S.C. § 112

Claims 70-72, 74-77, 79-80, 85, 99, and 139-148 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. More specifically, claim 70 is rejected for allegedly being vague and indefinite for reciting that the indication for treatment is selected from the group consisting of lupus or viral disease. The objected language has been omitted from the claim by amendment. Applicant respectfully submits that the claims are definite and requests withdrawal of the rejection under 35 U.S.C. § 112.

Claim rejections under 35 U.S.C. § 103

Claims 70-72, 74-77, 79-80, 85, 99, and 139-148 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Schwarting et al. (2001) in view of Pedersen et al. (U.S. Pat. No. 6,531,122) and Chang (U.S. Pat. No. 5,908,626) for the reasons of record. More specifically, the Examiner states:

Contrary to Applicant's assertion, there is a reasonable expectation of success of treating glomerulonephritis in a mammal by administering IFN- $\beta$  because the Schwarting et al. reference teaches that MRL-*Fas<sup>lpr</sup>* mice treated with IFN- $\beta$  show improvement in nephritis. . . [A]bsent evidence to the contrary treating the autoimmune condition with IFN- $\beta$  will treat glomerulonephritis and improve renal function. (*Office Action*, at p. 5).

Applicant respectfully traverses this rejection. However, to expedite prosecution, Applicant has amended claim 70 to recite a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN- $\beta$ . The particular combinations of references cited by the Examiner do not teach or suggest all of the claimed limitations. In particular, Schwarting et al. does not teach a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN- $\beta$ , as recited in Applicant's claim 70. Neither of the secondary references cited by the Examiner cure this deficiency.

Similarly, Schwarting et al. in view of Pedersen et al. and Chang et al. do not teach a method for treating glomerulonephritis in a mammal, consisting essentially of identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN- $\beta$  therapeutic, as recited in claims 143-144 and 148. The subject matter of claims 143-144 and 148 is such that identifying a mammal having an autoimmune disease is not required.

Further, to establish a *prima facie* case of obviousness, "a reasonable expectation of success is required." (MPEP §2143.02) Applicant respectfully submits that at the time of filing there existed no reasonable expectation of success that a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN- $\beta$ , comprising identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN- $\beta$  therapeutic, would be effective, absent the teachings of the present specification. Schwarting et al. (2001) teach treatment of an underlying lupus disease. Based on the teachings of Schwarting et al. in view of Pedersen et al. and Chang et al., one skilled in the art would have no reasonable expectation of success that IFN- $\beta$  treatment of glomerulonephritis would be effective absent amelioration of an underlying disease.

Additionally, Schwarting et al. teach away from the methods of Applicant's claims. The subjects treated with IFN- $\beta$  in Schwarting et al. are MRL-*Fas*<sup>lpr</sup> mice. Thus, Schwarting et al. teach away from treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN- $\beta$ .

Applicant respectfully submits that the claims are nonobvious and requests withdrawal of the rejection under 35 U.S.C. § 103.

### CONCLUSION

In view of the amendments and arguments presented above, Applicant believes the claims are in condition for allowance, which action is respectfully requested. If a telephone conversation with Applicant's Agent would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1749.

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Respectfully submitted,

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